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| APPLICATION NO.             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.        | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|----------------------------|------------------|
| 10/725,615                  | 12/03/2003  | Shabbir B. Bambot    | SPRX-0067C1                | 4991             |
| 34610 75                    |             |                      | EXAMINER  VALENTIN, JUAN D |                  |
| FLESHNER &<br>P.O. BOX 2212 |             |                      |                            |                  |
| CHANTILLY,                  |             |                      | ART UNIT                   | PAPER NUMBER     |
|                             |             |                      | 2877                       |                  |
|                             |             |                      | DATE MAILED: 05/17/2004    |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Application No. Applicant(s)  10/725,615 BAMBOT ET AL.  Examin r Art Unit   |
|---|
| Office Action Summany   |
| Examin r Art Unit   |
|   |
| Juan D Valentin II 2877   |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |
| Status  |
| 1) Responsive to communication(s) filed on <u>03 December 2003</u>  |
| - 2a). This action is <b>FINAL</b> 2b)⊠ This action is non-final.   |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |
| Disposition of Claims   |
| 4)⊠ Claim(s) <u>1-21</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  |
| 5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) <u>1-21</u> is/are rejected.  |
| 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.   |
| Application Papers  |
| 9)  The specification is objected to by the Examiner.  10)  The drawing(s) filed on 12/03/2003 is/are: a)  accepted or b)  objected to by the Examiner.   |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |
| Priority under 35 U.S.C. § 119  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |
| 1. Certified copies of the priority documents have been received.   |
| 2. Certified copies of the priority documents have been received in Application No  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |
| application from the International Bureau (PCT Rule 17.2(a)).   |
| * See the attached detailed Office action for a list of the certified copies not received.  |
|   |
| Attachment(s)   |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)   |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date   |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date 12/3/2003.  5) Notice of Informal Patent Application (PTO-152)  6) Other:   |

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### **DETAILED ACTION**

### **Drawings**

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the chamber opening with first and second transparent sides must be shown along with the second transparent side containing the sample while also providing for an aperture through which light from the light source to pass through to illuminate and interrogate the sample must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant defines terminology within the specification when referring to different embodiments of invention. In the claims the Applicant uses the same terminology, but Examiner cannot tell which embodiment of the specification the Applicant is claiming. When referring to Fig. 4, on page 6, line 2, Applicant discloses wherein "the chamber 425 has an opening...the

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second side of the chamber also provides for the containment of the sample while also providing for a window". Moving on to Fig. 6, discussed on page 7, line 28, Applicant discloses "directing a light source and the light collection device at the interrogation aperture 630 upon which light enters and reflects... and then is collected again through the aperture". While the specification may be enabling for the claim structure of claim 17, it is unclear as to how the claimed opening of claim 15 is incorporated with claimed aperture of claim 17. Examiner understands that the disclosed "window" is a synonym for the claimed "aperture", therefore enabling the claim structure for claim 17. For the purposes of clarifying and distinctly claiming the Applicants invention, Applicant is asked to please clear up discrepancies between the specification language and the claim language in order for Examiner and those of ordinary skill in the art to better understand the specific embodiments of Applicants invention.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless - .

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1-13, 15, 16 and 18-21 rejected under 35 U.S.C. 102(b) as being fully anticipated by Virtanen (USPN '581).

#### Claim 1

Virtanen in conjunction with Figs. 3, 15A, 15B discloses a system for measuring a characteristic of a sample (assay), the system comprising a light source, a light measuring device

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and a sample receptacle (sample preparation). Virtanen further discloses wherein the receptacle receives and emits light from the light source and wherein the emitted light is measured by the light-measuring device (col. 10, lines 19-56).

### Claim 2

Virtanen as applied above further discloses in conjunction with Figs. 15A & 15B a receptacle-comprising a reflective surface (mirror) and a chamber (cuvette) to store the sample (sample preparation) (col. 10, lines 19-56).

### Claim 3 & 4

Virtanen as applied above further discloses in conjunction with Fig. 3 at least one layer that comprises an access layer (cover, 24), a channel layer (assay sector, Fig. 4), and a base layer (col. 4, line 62-col. 5, line 63). It is inherent that the cover with inlet port 24 and assay sector make up the claimed access layer and channel layer. Further, it is inherent that the integrated bio-compact disk of Virtanen has some form of base layer that supports all the components disclosed.

# Claim 5

Virtanen as applied above further discloses wherein the access layer comprises an opaque reflective surface (Fig. 15B).

# Claim 6

Virtanen as applied above discloses wherein the access layer further comprises a first reflective access opening and a second reflective access opening (Fig. 3, refs. 22 & 23).

Claim 7

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Virtanen further discloses wherein the channel layer comprises a plurality of channel

layer openings coupled in communication with one another (Fig. 9, col. 11, lines 1-26).

Claim 8

Virtanen discloses wherein the plurality of openings is in alignment with the second

reflective opening (Figs. 3, 2B & 15B)

Claim 9

Virtanen further discloses wherein the base layer serves as the protective layer of the

receptacle such that the sample does not escape the channel layer after receipt from the access

layer (col. 4, line 62-col. 5, line 63). Applicant will be appreciated that the substrate layer reads

on the claimed limitation.

Claim 10

Virtanen as applied above further discloses wherein the at least one layer comprises a

plurality of layers coupled to one another (col. 4, line 62-col. 5, line 63).

Claim 11

Virtanen as applied above discloses wherein the at least one layer comprises a first layer

and a second layer (col. 4, line 62-col. 5, line 63).

Claim 12

Virtanen as applied above further discloses in conjunction with Figs. 2A & 15B wherein

the first layer comprises a reflective section (mirror) and the second layer comprise a chamber

(11) within (col. 10, lines 19-56).

Claim 13

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Virtanen further discloses wherein the reflective section and chamber are in alignment and in communication with each other Figs. 2A & 15B (col. 10, lines 19-56).

# Claim 15

Virtanen as applied above discloses further wherein the chamber comprises a chamber opening and a first transparent side and a second transparent side (see Fig. 15B).

# Claim 16

Virtanen as applied above further discloses wherein the first transparent side is also the cover of the chamber (see Fig. 15B).

### Claim 18

Virtanen as applied above further discloses wherein the receptacle comprises an integrated layer for filtering and analysis (Figs. 2A & 15B, col. 7, lines 36-64 & col. 10, lines 19-55).

# Claim 19

Virtanen as applied above further discloses wherein the integrated layer comprises an application port, a separation zone, a transport and detection zone, a reflective aspect, a transparent aspect, and an optical filter (Figs. 2A & 15B, col. 7, lines 36-64 & col. 10, lines 19-55).

# Claim 20

Virtanen as applied above further discloses wherein the integrated layer further comprises a reagent (col. 11, lines 1-26).

#### Claim 21

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The apparatus of Virtanen as applied above with regards to claim 1, can perform the claimed method.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claim 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen on view of Auad (USPN '783 B1).

# Claim 14

Virtanen substantially teaches the claimed invention except that it fails to show wherein the first layer and the second layer engages with an attachment of the light-measuring device. Auad shows that it is known to provide an attachment means to engage the receptacle to the light-measuring device (col. 7, lines 21-23 & col. 9, line 54-col. 10, line 5) for a fluid analysis system. It would have been obvious to someone of ordinary skill in the art to combine the device of Virtanen with the light measuring means attachment of Auad for the purposes of providing a secure stable apparatus.

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# Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juan D Valentin II whose telephone number is (571) 272-2433. The examiner can normally be reached on M-Th., Every other Fr..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank G Font can be reached on (571) 272-2415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Primary Petent Examiner

Technology Center 2800

Juan D Valentin II Examiner 2877 JDV

May 4, 2004